

**RECEIVED
CENTRAL FAX CENTER**

APR 26 2004

IN THE UNITED STATES PATENT OFFICE

OFFICIAL

| | | |
|--------------------------------------|---|---------------|
| Serial No. 10/748,996 | : | |
| Filed: 12/31/2003 | : | |
| Invention: Portable Handheld Hearing | : | |
| Screening Device and Method with | : | Art Unit 3736 |
| Internet Access and Link to Hearing | : | |
| Screening Database | : | |
| Inventor: Zoth et al. | : | |
| Examiner: | : | |

PRELIMINARY AMENDMENT

Commissioner of Patents
Washington, D.C. 20231

Sir:

Please amend the above-entitled continuation-in-part application to incorporate the changes required by Examiner Astorino in the parent application no 10/254,294 filed 9/25/2002 as follows:

In the Specification:

Please make the following changes to the specification as required by paragraph 1 of the Office Action:

1. Page 10, line 2, after "modems.", insert --Four handheld OAE and/or ABR Screening Devices are shown. The first interacts with the main database server via an external modem using analog, digital, cordless or wireless phone connections. The second interacts via a plug-in modem in contact with the main database server. The third interacts via an external modem in contact with the main database server, and the fourth interacts with the main database server via a built-in modem
2. Page 10, line 15, after "network.", insert ---Three handled OAE and/or ABR Screening Devices are shown. The first is connected via an external network adaptor to a local network server 1 interacting with the main database service. The second has a built-in network adaptor connected to the local network server 1 interacting with the main database server. The third is connected via a network adaptor to a local network server 2 interacting with the main database server.---

3. Page 10, line 21, after "Server.", insert—One handheld OAE and/or ABR Screening Device interacts with an internal/external modem connected via an internet/intranet connection to an internet/intranet service provider through an internet/intranet link to a database server.—
4. Page 10, line 23, delete "ia".
5. Page 10, line 26, after "management.", insert—Four handheld OAE and/or ABR screening devices are shown associated with separate regional servers connected to a database server. Two handheld OAE and/or ABR screening devices are shown connected to one regional server. The second two OAE and/or ABR screening devices are shown connected to a different regional server.---
6. To assist the Examiner in inserting the above changes disclosed in Figs 1 through 4, marked up pages 10 and 11 of the specification are shown below:

Fig. 1 illustrates the handheld screening devices connect to a central server via local modems. Four handheld OAE and/or ABR Screening Devices are shown. The first interacts with the main database server via an external modem using analog, digital, cordless or wireless phone connections. The second interacts via a plug-in modem in contact with the main database server. The third interacts via an external modem in contact with the main database server, and the fourth interacts with the main database server via a built-in modem. The screening devices communicate with a central server by actively establishing a dial-up or other connection. The handheld unit is able to store and memorize predefined phone numbers or these phone numbers can be entered via a keyboard similar to a handheld phone. The connection can be established via an analog or digital phone linen, via cordless or cellular phone channels or other media, such as power lines, fiber optic connections, etc. The modem can either be either external with power supplied from the screening device or an independent source, or internal. No local PC is needed. Nor does the user need to use any other device then the screener itself.

Fig. 2. illustrates how the portable screening devices contact a server via local networks. Three handled OAE and/or ABR Screening Devices are shown. The first is connected via an external network adaptor to a local network server 1 interacting with the main database service. The second has a built-in network adaptor connected to the local network server 1 interacting with the main database server. The third is connected via a network adaptor to a local network server 2 interacting with the main database server. The connection to the server could also be established through a local area network (LAN), which may be Ethernet, 'bluetooth' (wireless standard) or any other local area network. The screening device

establishes the connection without the user having to use any software on a local PC. Thus the screening device has a distinct advantage over other screening devices currently available on the market, which need a local PC to transfer data from the device.

Fig. 3 illustrates how the portable screening devices use global information network (internet) services to connect to the main server. One handheld OAE and/or ABR Screening Device interacts with an internal/external modem connected via an internet/intranet connection to an internet/intranet service provider through an internet/intranet link to a database server. Internet /Intranet services can be used in order to connect the screening device to the remote Server. The device can be connected to an Internet service provider via a telephone line or via WAP services (wireless application protocol). Measurement data and patient data can be exchanged on a special designed home page.

Fig. 4 illustrates the portable screening devices associated with Regional-Servers or WAN-servers used to de-centralize the data management. Four handheld OAE and/or ABR screening devices are shown associated with separate regional servers connected to a database server. Two handheld OAE and/or ABR screening devices are shown connected to one regional server. The second two OAE and/or ABR screening devices are shown connected to a different regional server.

These four figures illustrate a number of different set-ups to operate the handheld screening devices. The server side can be separated into a central server and several 'regional' servers to optimise data handling even in nationwide data management systems. Each regional server is connected to a certain number of devices, which are assigned thereto. The information as to which server to call and how to identify the server can be programmed by the screener. This programming can also be done by the supplier so that the end user does not need to configure anything.

The connection can then also be used for various other actions besides transferring measurement data:

- Send patient lists to the screener
- update or change configuration information on the devices
- transfer and install new software on the screener
- setting the real time clock of the screener
- transferring messages to the user, patient related, device related and service instructions

The service-issues messages may be dependent on measurement results. For example, if the refer-rate is too high, the server could recommend a recalibration of the instrument.

Although this specification has made reference to the illustrated embodiments, it is not intended to restrict the scope of the appended claims. The claims themselves recite those features deemed essential to the invention.

In the Claims:

Please amend the claims as follows:

Claim 1, Delete "etc."

Claim 10, delete the two "etc." references

Claim 1, delete the parenthetical information.

Claim 10, delete the parenthetical information.

Claim 3, delete "or other protocols" and insert —and—after "ftp-," and a period after "internet".

Claim 9, delete "like metabolic disease screening data."

Claim 12, delete "like metabolic disease screening data into the computer server".

Claim 1d, delete "such as an analog or digital phone line, cordless or wireless phone line, power line, fiber optic line, wireless LAN (blue tooth), satellite telephone line, internet phone,"

Claim 1e, delete "such as name, first name, mother's name, birth date, address, in/outpatient status, patient identification, hospital identification, patent history"

Claim 7b, delete "such as service-intervals, criterion measurement methods,"

Claim 7c, change "the" to—a—.

Claim 10d, delete "such as environmental noise, probe fit, electrode impedance, signal to noise ration, etc."

Claim 10e, delete "such as name, first name, mother's name, birth date, address, in-outpatient status, patient identification, hospital identification, patient history, etc."

To assist the present Examiner in locating the above corrections, marked up copies of the amended claims correcting the previous Examiner's 35 USC 112 objections are shown below:

1. (amended) A method for audiological screening of infants and newborns employing a handheld screening device having acoustic transmitters, microphone collection means, scalp electrodes, a digital signal processor, signal transmitters, receivers and a display screen comprising:

a. generating one or more stimuli with the acoustic transmitters of the handheld screening device in each ear canal of an infant or newborn,

b. collecting any transient evoked and/or distortion product otoacoustic emission signals generated by the cochlea in each ear canal in response to the stimulus with the microphone collection means placed in the ear, and/or collecting any click or frequency stimulated brainstem response signals by placing electrodes on the scalp,

c. analyzing the response signals using binomial statistics, different artifact categories by the digital signal processor,

d. transmitting all results ("pass", "refer", "technical error") all patient related data and all measurement relevant data (~~environmental noise, probe fit, electrode impedance, signal to noise ratio, etc.~~) from the handheld screening device transmitter to a patient tracking and screening system installed on a remote computer server via transmission means, ~~such as an analog or digital phone line, cordless or wireless phone line, power line, fiber optic line, wireless LAN (blue tooth), satellite telephone line, internet phone,~~ using an external or built-in modem like interface and a predefined protocol, and

e. receiving and displaying on the handheld screening device display screen all patient related data, ~~such as name, first name, mother's name, birth date, address, in/outpatient status, patient identification, hospital identification, patient history~~ directly from a patient tracking system installed on a main server via a link to the server.

3. (amended) A method according to claim 1, wherein the means to transmit the frequency mixed product electric signal from the audiologic screening device to a remote computer system comprises LAN connections to transfer and receive data in email-, ftp-, and internet or other protocols.

4. (amended) A method according to Claim 1, wherein the remote computer server receives and transmits screening and patient data via the patient tracking and screening system, which also controls the handheld screening device procedures with respect to:

- a. setting the real time clock of the screener user,
- b. providing program parameters, ~~such as service intervals, eriterions, measurement methods,~~
- c. uploading software upgrades to the a device.
- d. sending messages to the screener user, including service-issues and procedures.

9. (amended) A method according to Claim 1 including combining an audiologic screening database with other newborn screening data, ~~like metabolic disease screening data,~~ and using and accessing to a commonly used database on a computer or server which generates and then stores all patient and result data for different screening methods.

10. (amended) A device for audiological screening of infants and newborns comprising:

- a. means for generating one or more stimuli with acoustic transmitters in each ear canal of an infant or newborn,
- b. means for collecting any transient evoked and distortion product otoacoustic emissions generated by the cochlea in each ear canal in response to the stimulus with microphone means for generating a frequency mixed product electric signal, and brain stem responses via scalp attached electrodes,